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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/599,819

10/11/2006

Richard Heng

33739-US-PCT

5179

75074

7590

06/02/2010

NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.
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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT

PAPER NUMBER

1624

MAIL DATE

DELIVERY MODE

06/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,819	Applicant(s) HENG ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,7,11 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,11 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/2/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-5, 7, 11 and 17-20 are pending in the application.

This action is in response to applicants' amendment filed March 2, 2010. Claims 25-35, 39 and 41 have been amended and claims 42-56 are newly added.

Response to Amendment

Applicant's amendments filed March 2, 2010 have been fully considered with the following effect:

1. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 112, first paragraph rejection labeled paragraph 2) in the last office action, which is hereby **withdrawn**.

2. The applicants' amendments and arguments are sufficient to overcome the 35 U.S.C. § 112, second paragraph rejections labeled paragraphs 3d), e), f), g), h), t), u), v), w), dd), ee), ff), jj), kk), ll), mm), nn), oo), pp), qq), rr), ss), tt), uu), vv), xx), zz), aaa), bbb), ccc), ddd), eee), fff), ggg) and hh) in the last office action, which are hereby **withdrawn**. However, with regards to the 35 U.S.C. § 112, second paragraph rejections labeled paragraph 3a), b), c), i), j), k), l), m), n), o), p), q), r), s), x), y), z), aa), bb), cc), gg), hh), ii), ww) and yy) in the last office action, the applicant's amendments have been fully considered but they are not persuasive.

a) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the

definition of R1, R2 and R3 as well as the definition of R4 in claim 1 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the oxy -O-.

Claims 1-5, 7, 11 and 17-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

b) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of R1, R2 and R3 as well as the definition of R4 in claim 1 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the carbonyl -C(O)-.

Claims 1-5, 7, 11 and 17-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

c) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of R1, R2 and R3 as well as the definition of R4 in claim 1 simply states

substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the sulfur -S-.

Claims 1-5, 7, 11 and 17-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

i) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R1, R2, R3 and R4 in claim 1 simply states substituted oxy, sulfur, sulfinyl, sulfonyl and fails to specify exactly what is attached to the oxy -O-.

Claims 1-5, 7, 11 and 17-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

j) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R1, R2, R3 and R4 in claim 1 simply states substituted oxy, sulfur, sulfinyl, sulfonyl and fails to specify exactly what is

attached to the sulfinyl and sulfonyl.

Claims 1-5, 7, 11 and 17-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

k) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R1, R2, R3 and R4 in claim 1 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the sulfur -S-.

Claims 1-5, 7, 11 and 17-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

l) The applicants' stated that R1 is defined as being a substituted carbonyl group which the carbonyl is substituted with amino, and which amino can be further substituted with alkyl, therefore the amide group such as for example C(O)NH₂ or C(O)-N(alkyl)₂, or C(O)-NH-alkyl. The applicants' also indicated that "sulfonyl" has antecedent basis in claim 1, such that sulfur is defined on page 9 to include sulfonyl group -SO₂- and the term sulfonamide such as for example -

SO₂NH₂ or -SO₂NH-alkyl has sufficient antecedent basis where R1 is defined to be a substituted sulfur. However, the definition of R1 in claim 1 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the carbonyl -C(O)- or sulfur -S-. Additionally the specification does not define sulfur to include the sulfonyl group.

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

m) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R1 in claim 2 simply states substituted oxy and fails to specify exactly what is attached to the oxy -O-.

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

n) The applicants' stated that the term "heterocycloalkyl" is listed in the definition of R1 in claim 1 (the 10th variable for R1 in amended claim 1) and therefor has antecedent basis. However, the lack of antecedent basis of the term "heterocycloalkyl" is based on the list of substituents on R1 and not R1 itself.

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being

indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

o) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R1 in claim 2 simply states substituted sulfinyl, sulfonyl and fails to specify exactly what is attached to the sulfinyl, sulfonyl.

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

p) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R1 in claim 2 simply states substituted sulfur and fails to specify exactly what is attached to the sulfur -S-.

Claim 2 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

q) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the

definition of R1" and R2" in claim 4 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the oxy -O-.

Claims 4 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

r) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of R1" and R2" in claim 4 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the carbonyl -C(O)-.

Claims 4 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

s) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of R1" and R2" in claim 4 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the sulfur -S-.

Claims 4 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as

being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

x) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R1" and R2" in claim 4 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the oxy -O-.

Claims 4 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

y) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R1" and R2" in claim 4 simply states substituted sulfinyl, sulfonyl and fails to specify exactly what is attached to the sulfinyl, sulfonyl.

Claims 4 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated

above.

z) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R₁" and R₂" in claim 4 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the sulfur -S-.

Claims 4 and 7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

aa) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of R₁", R₂" and R₃" as well as the definition of R₄" in claim 5 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the oxy -O-.

Claims 5, 7 and 20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

bb) The applicants' stated that claims 1, 2, 4 and 5 have been amended to

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incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of R_1 , R_2 and R_3 as well as the definition of R_4 in claim 5 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the carbonyl -C(O)-.

Claims 5, 7 and 20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

cc) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of R_1 , R_2 and R_3 as well as the definition of R_4 in claim 5 simply states substituted oxy, carbonyl, sulfur and fails to specify exactly what is attached to the sulfur -S-.

Claims 5, 7 and 20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

gg) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly

define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R₁', R₂', R₃' and R₄' in claim 5 simply states substituted oxy and fails to specify exactly what is attached to the oxy -O-.

Claims 5, 7 and 20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

hh) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R₁', R₂', R₃' and R₄' in claim 5 simply states substituted sulfinyl, sulfonyl and fails to specify exactly what is attached to the sulfinyl, sulfonyl.

Claims 5, 7 and 20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

ii) The applicants' stated that claims 1, 2, 4 and 5 have been amended to incorporate the definition of the term oxy, carbonyl and sulfur and to more clearly define their substitution, which allows to meet the desired valency. However, the definition of the substituents on R₁', R₂', R₃' and R₄' in claim 5 simply states

substituted sulfur and fails to specify exactly what is attached to the sulfur -S-.

Claims 5, 7 and 20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

ww) The applicants' stated that the rejection is rendered moot by deletion of terms and/or phrases in claim 17. However, the definition of the variables Y', Z', Q' and R₄' in formula IX which are still not defined.

Claims 17 and 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

yy) The applicants' stated that the rejection is rendered moot by deletion of terms and/or phrases in claim 17. However, the definition of the variables R₁', R₂', R₃', Y', Z', Q' and R₄' in formula XI which are still not defined.

Claims 17 and 18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record and stated above.

3. The applicants' amendments are sufficient to overcome the 35 U.S.C. § 101 rejection labeled paragraph 4) in the last office action, which is hereby **withdrawn**.

In view of the amendment dated March 2, 2010, the following new grounds of rejection apply:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-5, 7, 11 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amendment to claims 1 and 5 wherein sulfur represents -S(O)- or -S(O)₂- is not described in the specification with respect to formula (I).

Applicant is required to cancel the new matter in the reply to this Office action.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 7, 17, 18 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reason(s) apply:

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- a. Claim 7 is vague and indefinite in that it is not known what is meant by “respectively” which is believed that formula I from claim 1, Ia from claim 4, and II from claim 5, which is not so.
- b. Claim 17 and claims dependent thereon are vague and indefinite in that it is not known what is meant by the structures of formulae IX and XI.
- c. Claim 20 recites the limitation "R1', R2' and R3'" in the first line claim 20. There is insufficient antecedent basis for this limitation in the claim. Claim 5 is to the variables R_1' , R_2' and R_3' .

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brenda L. Coleman/
Primary Examiner, Art Unit 1624